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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,206	MCDOUGALD ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/3/04 & 6/25/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-14 are currently under examination.

Claim Objections

2. Claims 7 and 9 are objected to because of the following informalities: there is an inappropriate spacing in the words "o f" and "c omposition" in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5, 8, 9, 12, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites that the ratio of *E.acervulina:E.maxima:E.mitis:E.tenella* is about "10:1 to 2:10:2 to 5". This is vague and confusing. What strains do the '10:1' represent, the '2:10:2' and the '5'? There are four strains recited in the claim and it is vague and confusing which amount of the recited ranges reflects which strain since the ratio does not match the number of strains recited.

Claim 5 and 12 are also vague and confusing do to the recited ratio of 5:1:5:1. Does this mean 5 oocysts of *E.acervulina,* 1 oocyst of *E.maxima*; 5 oocysts of *E.mitis*; and 1 oocyst of *E.tenella*, e.g., 500 oocysts of *E.acervulina,* 100 oocyst of *E.maxima*; 500 oocysts of *E.mitis*; and 100 oocyst of *E.tenella,* or something else? Clarification is requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "vaccine compositions for protection against *E.tenella, E.maxima, E.acervulina* and *E.mitis* consisting essentially of a mixture of sporulated oocysts isolated from precocious strains of *E.tenella, E.maxima, E.acervulina* and *E.maxima"* and methods for inducing a protective immune response against *E.tenella, E.maxima, E.acervulina* and *E.maxima* through the administration of said vaccine, does not reasonably provide enablement for 'vaccines or protective methods which cross protect against all species of *Eimeria'* as instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are broadly drawn to 'vaccines or protective methods which cross protect against all species of *Eimeria'*. The prior art teaches many different vaccines against coccidiosis and teaches that sporulated oocysts from any or all of the seven *Eimeria* species that parasitize chicken (*E.tenella, E.maxima, E.acervulina, E.brunetti, E.necatrix, E.praecox* and *E.mitis* may be used in the compositions. The prior art teaches that there is no cross-protection between coccidial species of the same host. Hence all seven of the species known to parasitize the domestic fowl are required

in vaccine for it to prevent coccidial disease. See page 4, column 1, of Williams et al, listed as document 'U" on the IDS submitted on 6/25/04. The instant vaccine compositions and methods of protection encompass protecting against coccidial disease and all species of *Eimeria* since they do not specifically state what the vaccine protects against. The instant specification has only demonstrated that the instantly claimed vaccines can protect against challenge with the species of strains included in the vaccine composition, e.g., *E.tenella, E.maxima, E.acervulina* and *E.mitis.* The vaccine has not been shown to provide protection against the other 3 species of *Eimeria* based on the prior art teachings it is highly unpredictable that the vaccine would have the ability to protect against these other species as it is taught that there is no cross-protection between coccidial species of the same host. Accordingly, the scope of invention is not enabled. It is also noted that that the challenge experiments instantly described only included challenge of the components present in the claimed vaccine, e.g., *E.tenella, E.maxima, E.acervulina* and *E.mitis.* However, the commercial vaccine to which it is being compared comprises *E.tenella, E.maxima, E.acervulina and* ***E.mivati***. No *E.*mitis is present in the commercial vaccine. The two vaccines do not contain the same species of *Eimeria*. Accordingly, the challenge experiments are not equivalent and this may explain why the claimed vaccine showed less mortality than that of the commercial vaccine. It is not an equal experiment. Additionally, the specification refers to the "Schering-plough vaccine" in Table 6 yet it refers to the "Coccivac-B' vaccine in Table 9. It is unclear that these are the same vaccines. Clarification is requested.

The instant claims should be limited to the enabled scope or additional evidences should be provided.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmatz et al (WO 94/16725).

Schmatz et al teach vaccines comprising attenuated precocious oocysts from two to all seven of the common species of *Eimeria* (*E.acervulina, E.maxima, E.tenella, E.mitis, E.necatrix, E.praecox* and *E.brunette)*. It is taught that the particular content of the polyvalent vaccine may be adjusted to contain different species depending on local conditions and the prevalence of particular species in a certain area. See page 2, lines 20-33. It is taught that the precise number of each species present in the polyvalent vaccine will vary depending on the specific level of infectivity of each species and it will be normal to have a vaccine with different numbers of each species to reflect such different characteristics of each species. See page 3, lines 23-28.

9. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (WO 96/40234) which corresponds to US Patent no. 6,495,146 B1.

Evans et al (WO 96/40234) teach vaccines comprising sporulated oocysts from two **or more** precocious strains of *Eimeria* selected from the group consisting of *E.acervulina, E.maxima, E.tenella, E.mitis, E.necatrix, E.praecox* and *E.brunette.* See page 4, lines 9-12 and claim 8. Page 3, lines 1-10, recite that the strains are precocious or attenuated. This scope allows for vaccines comprising sporulated oocysts from precocious strains of just *E.acervulina, E.maxima, E.tenella,* and *E.mitis* as instantly claimed. Methods for inducing an immunological or protective response comprising administering the vaccine composition are also taught.

10. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald et al. (US 5,055,292).

McDonald et al teach vaccines against coccidiosis which comprise sporulated oocysts from live, attenuated strains of at least *E.acervulina, E.maxima* and *E.tenella.* It is taught that additional sporulated oocysts from other live, attenuated strains of *Eimeria*, including *E.mitis*, may be added to the composition. This scope allows for vaccines comprising sporulated oocysts from precocious strains of just *E.acervulina, E.maxima, E.tenella,* and *E.mitis* as instantly claimed. Methods for inducing an immunological or protective response comprising administering the vaccine composition are also taught. McDonald allows for a vaccine comprising sporulated oocysts from precocious strains of at least *E.acervulina, E.maxima* and *E.tenella*, and additionally *E.mitis.*

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 2-5 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Schmatz et al (WO 94/16725), Evans et al (WO 96/40234), or McDonald et al. (US 5,055,292).

The teachings of Schmatz, Evans and McDonald are set forth above. Although they do not specifically recite the exact ratios or ranges of the oocysts as recited in claims 2-5 and 8-14, it would have been obvious to one of ordinary skill in the art to vary the ratio/range of oocysts to a range which is optimal. Further, Schmatz specifically teaches that the precise number of each species present in the polyvalent vaccine will vary depending on the specific level of infectivity of each species and it will be normal to have a vaccine with different numbers of each species to reflect such different characteristics of each species and both Evans and McDonald teach that the range of oocysts per species will vary. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an

optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific ratios or ranges recited in instant claims 2-5 and 8-14 are for any particular purpose or solve any stated problem and the prior art teaches that the numbers of oocysts often vary according to the particular situation or the level of infectivity of species, and the vaccines/methods appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the vaccines/methods disclosed by the prior art by normal optimization procedures known in the vaccine art.

13. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 9/27/04

Jennifer Graser
Primary Examiner
Art Unit 1645